

REMARKS

Claims 21 through 49 were pending in the application. By this amendment, claims 21 and 43 have been amended. Reconsideration and withdrawal of the rejections is requested in view of the foregoing changes to the claims and the following remarks.

The following remarks are intended to address all of the grounds for rejecting the claims set forth in the pending Office Action.

I. Claim Rejections under 35 U.S.C. § 103(a)

Claims 21-23, 25, 43-45, and 47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kortenbach et al. (USP 7,232,445) in view of Crockard (USP 5,174,276). In addition, claims 24, 36, 40-42, and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kortenbach ('445) and Crockard in further view of Kortenbach et al. (USP 6,569,085). Also, claims 37-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kortenbach ('445), Crockard, and Kortenbach ('085) in further view of Reed (US 2003/0165887). Finally, claims 21-23, 26-35, 43,44, 46, 48, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kalloo et al. (US 2002/0022851) in view of Crockard. Without acceding to the grounds for rejecting the claims, Applicant responds as follows.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Turning first to the claims, claim 21 recites a method for performing a medical procedure that includes, *inter alia*, the steps of advancing an overtube within a hollow body organ in a flexible state, transitioning the overtube to a rigid state, advancing a plication device through the overtube, and forming a tissue fold within the hollow body organ with the plication device. By the present amendment, claim 21 has been amended to recite the additional method step of "securing the tissue fold using a tissue anchor deployed from a needle of the plication device." Support for these amendments is provided throughout the specification, such as, for example, at paragraphs 0083-0092, and at FIGS. 3D-E, 4A-C, and 5A-B. For example, paragraph 0086 of the specification states the following in relation to FIG. 3E of the application, which is reproduced below:

As depicted in FIG. 3E, after tissue fold F is stretched across distal tip 24 of flexible tube 14 to form contact point P2 with tissue wall W, needle 34 may be extended from distal tip 24 and through tissue fold F. Because needle 34 penetrates the tissue wall twice, it exits within the gastrointestinal lumen, thus reducing the potential for injury to surrounding organs. Once the needle has penetrated tissue fold F, an anchor assembly is ejected through distal tip 24 as described hereinbelow.

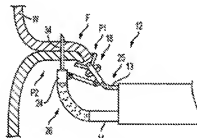
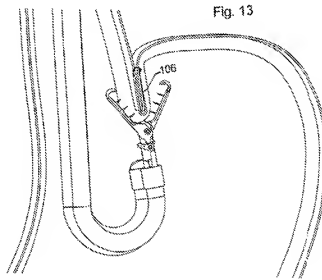


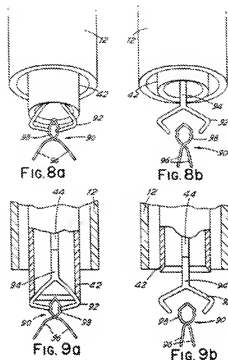
FIG. 3E

As for claim 43, that claim recites a method for performing a medical procedure that includes, *inter alia*, the steps of advancing a main body having a plication device within a hollow body organ in a flexible state, transitioning the main body to a rigid state, and forming a tissue fold within the hollow body organ with the plication device. By the present amendment, claim 43 has also been amended to recite the additional method step of "securing the tissue fold using a tissue anchor deployed from a needle of the plication device." Support for these amendments is the same as that described above for the amendments to claim 21.

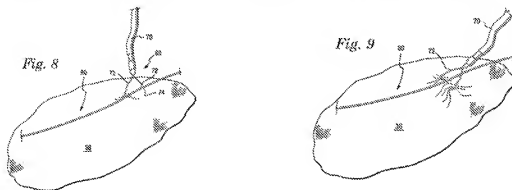
As noted above, each of claims 21 and 43 was rejected as being unpatentable over the combinations of: (a) the Kortenbach '445 patent and the Crockard patent, and (b) the Kalloo publication and the Crockard patent. None of these references, however, describes or suggests a method that includes the step of "securing the tissue fold using a tissue anchor deployed from a needle of the plication device," as recited in claims 21 and 43 as amended. For example, the Kortenbach '445 patent describes a device that deploys a clip (106) over the tissue without the use of a needle, as shown in Fig. 13 below:



The Crockard patent, on the other hand, describes a device that deploys an aneurysm clip 90 to an aneurysm without the use of a needle, as shown in Figs. 8a-b and 9a-b below:



Finally, the Kalloo publication describes a clip fixing device applicator 70 that deploys a clip fixing device 68 without the use of a needle, as shown in Figs. 8 and 9 below:



Accordingly, none of the Kortenbach '445, Crockard, or Kalloo references teaches a method that includes a step of "securing the tissue fold using a tissue anchor deployed from a needle of the plication device."

Similarly, none of the other references relied upon in the Office Action to reject any of the dependent claims contains any teaching or suggestion of the method step of

“securing the tissue fold using a tissue anchor deployed from a needle of the plication device.”

Accordingly, because at least the foregoing elements recited in each of claims 21 and 43 are not disclosed, taught, or suggested by the Kortenbach '445, Crockard, or Kalloo references, either alone or in combination with any of the other cited references, there can be no prima facie case of obviousness of either of claims 21 or 43. These claims, and all of their dependent claims (i.e., claims 22-42 and 44-49), should be allowed.

Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, but rather as an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02512**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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